

REMARKS

Substance of Interview

Applicants and the undersigned thank the Examiner Shin Lin Chen for conducting the telephonic interview of 14 December 2010 and for accommodating the schedule of the undersigned. In accordance with MPEP § 713.04, substance of interview is provided herein. In summary, the undersigned and the Examiner discussed the outstanding rejections to claims 22 and 24. The undersigned noted that the description of ATCC Deposit No. PTA-10532 (25 vials) was provided in ATCC's Certificate of 13 October 2009, filed as an Appendix along with the previous amendment of 14 February 2010. The Examiner admitted that he inadvertently overlooked the Certificate and that the content of ATCC Deposit No. PTA-10532 is clear in view of the description in the Certificate. The Examiner further noted that this clarification would overcome the outstanding indefiniteness rejection and the portion of the enablement rejection directed to the contents of the biological deposit.

The Claims are Not Indefinite

The Office Action of 22 September 2010 rejected claims 22 and 24 as allegedly indefinite because "[t]here is no description of what is contained in the ATCC Deposit No. PTA-10532." *Office Action of 22 September 2010*, page 2.

As discussed during the Examiner interview, Applicants respectfully note that the disclosure of ATCC's Certificate of 13 October 2009 renders moot the above indefiniteness rejection. Specifically, the Certificate sufficiently describes the deposit at issue, including 25 vials, as "[n]on-replicating vector based on the human adeno virus serotype-5 with E-1 deleted and insert of human MMP-8 expression: Ad-MMP-8." *ATCC's Certificate of 13 October 2009*. Accordingly, Applicants respectfully request reconsideration and withdrawal of the indefiniteness rejection.

The Claims are Fully Enabled

The Office Action of 22 September 2010 rejected claims 22 and 24 because the specification allegedly fails to enable the claimed invention. Applicants respectfully disagree and assert that the specification enables the full scope of the presently claimed invention.

In making the rejection, the Examiner states, "it is unclear what kind of material or adenoviral vector is contained in the ATCC Deposit No. PTA-10532 other than pcDNA-MMP-8 with CMV promoter

... ." *Office Action of 22 September 2010*, page 3. In response, Applicants respectfully note, as explained above, that ATCC's Certificate of 13 October 2009 sufficiently describes the deposit at issue.

Further, Applicants have amended the claims to better capture the envisioned commercial embodiments and assert that the amendments render moot the enablement rejection. Specifically, claim 24 is directed towards delivering MMP-8 to the liver of subjects. Applicants assert that the specification provides ample guidance and evidence that the target of the administered viral particles is primarily and predominantly the liver. *See* Pages 12-16 of the Specification. In fact, the Examiner has indicated the specification makes it clear that the adenoviral particles disclosed in the specification target the liver. In addition, as discussed in the previous Amendment of 14 February 2010, this same passage in the specification provides ample guidance to one of skill in the art for delivering the target to hepatocytes.

In making the rejection, the Examiner states that "there is no evidence of record that shows intravenous administration of the claimed composition would provide sufficient therapeutic protein at target site so as to provide therapeutic effects in target organs for treating hepatic fibrosis in a subject." *Office Action of 22 September 2010*, page 4. With respect to the therapeutic effects in target organs, however, Applicants respectfully submit that the claim amendments render this portion of the enablement rejection moot as the claims now read on "delivering" the protein to the liver of a subject instead of treating a subject.

For the reasons set forth above, Applicants assert that the specification is fully enabling with respect to the claims as they currently stand, such that one of skill in the art would be able to practice the full scope of the claimed invention without undue experimentation. Applicants respectfully request reconsideration and withdrawal of the enablement rejection.

CONCLUSION

Applicants have amended the claims to better capture the envisioned commercial embodiments and to insert deposit information into the specification. Applicants assert that the amendments do not introduce new matter. In addition, Applicants assert that the amendments to the claims render moot the remaining rejections.

The Examiner is invited to contact the undersigned at the telephone number listed below if discussion of any remaining issues would better advance prosecution.

Respectfully submitted,

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